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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/666,744 | 09/15/2003 | John J. Quinn | 1300-0008 | 6795 |

23980 7590 11/27/2006

MINTZ, LEVIN, COHN, FERRIS, GLOVSKY AND POPEO, P.C
1400 PAGE MILL ROAD
PALO ALTO, CA 94304-1124

EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 11/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/666,744 | Applicant(s) QUINN ET AL. | |
| | Examiner Bradley L. Sisson | Art Unit 1634 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 28-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06 November 2006 has been entered.

Election/Restrictions

2. Applicant's election with traverse of Group I, claims 1-27, in the reply filed on 27 April 2006 is acknowledged. The traversal is on the ground(s) that the recitation of "capture probes" in the two sets, where one set positively recites the presence of a support to which the probes are attached to a substrate, while the other set of claims does not recite the attachment of probes to a substrate, should not render the claims distinct as they are both identified as being "capture probes." This is not found persuasive because the claims of the kit recite that the kit comprises "hybridization probes," which can comprise a "capture sequence." There is no limitation being recited that the hybridization probe is immobilized or is in any way bound to a substrate. It is further noted that the kit may also comprise first and second "capture probes," which are immobilized to first and second substrates. Those components that are not bound are properly classified in Class 536, subclass 24.3, and those probes that are immobilized are properly

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classified in Class 435, subclass 287.2. In each instance, the components of the kit are distinct from the method of Group I, which is properly classified in class 435, subclass 6.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 28-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 27 April 2006.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,228,575 B1 (Gingeras et al.) in view of US Patent 6,753,143 B2 (Tao et al.) and US Patent 6,268,147 B1 (Beattie et al.).

8. Gingeras et al., teach of hybridizing fluorescently-labeled amplicons to immobilized probes, and detecting the resultant signal, where different intensities and patterns of hybridization are indicative of the amplicons being derived from different species or variants of species.

9. While Gingeras et al., do teach of hybridizing the amplicons to immobilized probe, they have not been found to teach that the probes are also hybridized to a common sequence on the support.

10. Tao et al., Figure 4B, and at column 2, disclose a preferred embodiment of conducting a hybridization assay. As depicted in said Figure 4B, a common capture probe is immobilized to a support, to which is hybridized a "capture extender probe" (applicant's "differential hybridization probe"), which is comprised of two regions: a first region that hybridizes to the target and a second region that hybridizes to a region of the capture probe.

11. Tao et al., column 9, disclose a multitude of suitable materials that can serve as a support.

12. Tao et al., column 49, third paragraph, teaches that the target analyte itself can be labeled.

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13. Tao et al., column 73, third paragraph, teach using the method for detecting mutations in genes. Such speaks directly to determining if a sample is comprised of wild type or variant sequences.

14. Neither Gingeras et al., nor Tao et al., have been found to disclose using polymorphic markers, or sorting the hybridization mixture on the basis of flow cytometry.

15. Beattie et al., column 11, second paragraph, teaches the use of differential hybridization probes where the polymorphic site of interest is located either an internal or a terminal position. Beattie et al., column 20, last paragraph, teaches explicitly of using differential hybridization probes that hybridize to not only the “wild type” sequence, but also differential hybridization probes that hybridize specifically to a known mutant allele.

16. Beattie et al., teach said hybridization complexes can be detected by autoradiography, microarray analysis, and fluorescence imaging that can detect fluorescence or chemiluminescence such as flow cytometry utilizing immobilized capture probes on beads (columns 26, lines 65-67, column 19, lines 24-30, column 30, lines 21-30, and column 38, lines 36-47 and Figures 1 and 15).

17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Gingeras et al., to have incorporated the use of the preferred embodiment of Tao et al., as represented in Fig. 4B as such would have allowed of the production of a common support comprising a common capture probe as such would have effectively eliminated the need and expense of developing a probe assortment on each substrate. And it would have also been obvious to one of ordinary skill in the art to have modified the support of Tao et al., such that it would accommodate flow cytometry, as disclosed by Beattie et

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al., as such would have eliminated the time, effort, and expense of preparing the electrode connections of Tao et al., and capitalized on the well-developed and inexpensive practice of flow cytometry.

18. In view of the foregoing remarks, and in the absence of convincing evidence to the contrary, claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,228,575 B1 (Gingeras et al.) in view of US Patent 6,753,143 B2 (Tao et al.) and US Patent 6,268,147 B1 (Beattie et al.).

Conclusion

19. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS